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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee (formerly Drug Abuse Advisory Committee).

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 17, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–021), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (for Express delivery: 5630 Fishers Lane, Room 1093, Rockville MD 20857), 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss ways to improve the usefulness of consumer medication information (CMI) distributed with prescriptions being filled at the nation's pharmacies. Findings of a recent FDA-sponsored study(www.fda.gov/ohrms/dockets/ac/acmenu.htm) showed that CMI is currently being distributed with more than 85 percent of prescriptions and that scientific accuracy of the materials is high, but the usefulness of materials is variable due largely to omissions of important risk and benefit information. The committee will consider: (1) Potential causes of

insufficiencies in CMI, including current practices of the parties involved in developing and processing CMI and pharmacy practices that may affect the distribution and content of CMI, and (2) potential interventions to address causes of CMI insufficiencies in the current system, and scientific methods to assess and monitor whether effective communication of key information to patients is occurring.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 15, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 15, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly L. Topper by July 15, 2002.

FDA regrets that it was unable to publish this notice 15 days prior to the Drug Safety and Risk Management Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Drug Safety and Risk Management Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15–day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2).

Dated: July 5, 2002.

William K. Hubbard,
Senior Assoicate Commissioner for Policy, Planning, and Legislation.

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